Clmspto for allowance

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1. (Currently Amended) A method for predicting a hypoglycemic event in a subject, said method comprising

determining (i) a threshold glucose value that corresponds to said hypoglycemic event, and (ii) ~~at least one threshold parameter value that is correlated with said hypoglycemic event, wherein~~ ~~at least one~~ a threshold ~~parameter value is~~ skin conductance and/or temperature value that is correlated with said hypoglycemic event;

obtaining a series of glucose measurement values at selected time intervals using a method comprising

~~extracting a sample comprising glucose from the subject using a transdermal sampling system that is in operative contact with a skin or mucosal surface of said subject;~~

obtaining a raw signal specifically related to a glucose amount or concentration in the subject for a given time interval;

correlating the raw signal with a glucose measurement value indicative of the amount or concentration of glucose present in the subject ~~at the time of extraction~~ in said given time interval;

repeating said obtaining and correlating to provide a series of glucose measurement values at selected time intervals;

predicting a glucose measurement value at a further time interval subsequent to said series of glucose measurement values; and

comparing said predicted glucose measurement value to said threshold glucose value, wherein when the ~~a~~ predicted glucose measurement value is less than or equal to ~~lower than~~ the threshold glucose value ~~is designated to be~~ a hypoglycemic event is predicted;

measuring skin conductance and/or temperature of the subject ~~at least one parameter value or trend of parameter values~~ concurrently, simultaneously, or sequentially with said obtaining of the series of glucose measurement values, ~~wherein the parameter value or trend of parameter values is (i) correlated with said hypoglycemic event, and (ii) reflective of skin conductance readings or temperature readings of the subject,~~ and comparing said ~~parameter~~ skin conductance and/or temperature value or trend of ~~parameter~~ skin conductance and/or temperature values with said threshold ~~parameter~~ skin conductance and/or temperature value to determine whether said ~~parameter~~ skin conductance and/or temperature value or trend of ~~parameter~~ skin conductance and/or temperature values indicates a hypoglycemic event; and

predicting a hypoglycemic event in said subject when both (i) comparing ~~said~~ the predicted glucose measurement value to said threshold glucose value indicates a hypoglycemic event at said further time interval, and (ii) comparing said ~~parameter~~ skin conductance and/or temperature value or trend of ~~parameter~~ skin conductance and/or temperature values with said threshold ~~parameter~~ skin conductance and/or temperature value indicates a hypoglycemic event.

14. (Original) The method of claim 1, wherein said obtaining of the series of glucose measurement values is performed using a near-IR spectrometer.

5. (Currently Amended) The method of claim 1, wherein ~~parameter~~ the values or trend of ~~parameter~~ values for both skin conductance readings and temperature readings are used to predict the likelihood of a hypoglycemic event at said further time interval.

2. (Original) The method of claim 1, wherein the selected time intervals are evenly spaced.

3. (Currently Amended) The method of claim 1, wherein the series of glucose measurement values comprises three or more discrete glucose measurement values.

4. (Currently Amended) The method of claim 3, wherein the further time interval occurs one time interval after the series of glucose measurement values.

6. (Currently Amended) The method of claim 3, wherein said predicting of the glucose measurement value at a further time interval is carried out using said series of three or more glucose measurement values in a series function represented by:

$$y_{n+1} = y_n + \alpha(y_n - y_{n-1}) + \frac{\alpha^2}{2}(y_n - 2y_{n-1} + y_{n-2}) \qquad (7)$$

wherein $y$ is the measurement value of glucose, $n$ is the time interval between glucose measurement values, and $\alpha$ is a real number between 0 and 1.

7. (Currently Amended) The method of claim 6, wherein the series function is used to predict the value of $y_{n+1}$ wherein time interval n+1 occurs one time interval after the series of glucose measurement values is obtained.

10. (Previously Presented) The method of claim 1, wherein a sample comprising glucose is extracted from the subject into one or more collection reservoirs to obtain an amount or concentration of glucose in a reservoir.

12. (Currently Amended) The method of claim 10 ~~11~~, wherein at least one collection reservoir comprises an enzyme that reacts with the extracted glucose to produce an electrochemically detectable signal to provide said raw signal.

11. (Original) The method of claim 10, wherein the one or more collection reservoirs are in contact with the skin or mucosal surface of the subject and the sample is extracted using an iontophoretic current applied to said skin or mucosal surface.

13. (Original) The method of claim 11, wherein said enzyme is glucose oxidase.

15. (Currently Amended) A glucose monitoring system for measuring glucose in a subject, said system comprising, in operative combination:

a sensing mechanism in operative contact with the subject or with a glucose-containing sample extracted from the subject, wherein said sensing mechanism obtains a raw signal specifically related to glucose amount or concentration in the subject;

a first device to obtain skin conductance readings or temperature readings from the subject; and

one or more microprocessors in operative communication with the sensing mechanism, wherein said microprocessors comprise programming to (i) control the sensing mechanism to obtain a series of raw signals at selected time intervals, (ii) correlate the raw signals with glucose measurement values indicative of the amount or concentration of glucose present in the subject to obtain a series of glucose measurement values, (iii) predict a glucose measurement value at a further time interval, which occurs after the series of glucose measurement values is obtained, (iv) compare said predicted glucose measurement value to a predetermined glucose value, wherein a predicted glucose measurement value ~~lower~~ less than or equal to the predetermined glucose value is designated to be hypoglycemic, (v) control the first device for measuring skin conductance readings or temperature readings of the subject, (vi) compare said skin conductance readings or temperature readings with a threshold ~~parameter~~ skin conductance or temperature value or trend of skin conductance or temperature ~~parameter~~ values to determine whether said skin conductance readings or temperature readings indicate a hypoglycemic event, and (vii) predict a hypoglycemic event in said subject when both (a) comparing said predicted glucose measurement value to said threshold glucose value indicates a hypoglycemic event at said further time interval, and (b) comparing said skin conductance readings or temperature readings with a threshold skin conductance or temperature ~~parameter~~ value or trend of skin conductance or temperature ~~parameter~~ values indicates a hypoglycemic event.

16. (Original) The monitoring system of claim 15, wherein the sensing mechanism comprises a biosensor having an electrochemical sensing element.

17. (Original) The monitoring system of claim 15, wherein the sensing mechanism comprises a near-IR spectrometer.

18. (Previously Presented) The monitoring system of claim 15, wherein said first device to obtain said skin conductance readings is a sweat probe.

19. (Previously Presented) The monitoring system of claim 15, wherein said first device to obtain said temperature readings is a temperature probe.

35. (Previously Presented) The monitoring system of claim 15, further comprising a second device and wherein said first device comprises a sweat probe to obtain said skin conductance readings and said second device comprises a temperature probe to obtain said temperature readings.

23. (Previously Presented) The monitoring system of claim 35, wherein both skin conductance readings and temperature readings are used to predict the likelihood of a hypoglycemic event at the further time interval.

20. (Original) The monitoring system of claim 15, wherein the selected time intervals are evenly spaced.

21. (Currently Amended) The monitoring system of claim 15, wherein the series of glucose measurement values obtained comprises three or more discrete glucose measurement values.

22. (Currently Amended) The monitoring system of claim 21, wherein the further time interval occurs one time interval after the series of glucose measurement values.

24. (Currently Amended) The monitoring system of claim 21, wherein said predicting of a glucose measurement value at a further time interval is carried out using said series of three or more glucose measurement values in a series function represented by:

$$y_{n+1} = y_n + \alpha(y_n - y_{n-1}) + \frac{\alpha^2}{2}(y_n - 2y_{n-1} + y_{n-2}) \qquad (7)$$

wherein $y$ is the measurement value of glucose, $n$ is the time interval between glucose measurement values, and $\alpha$ is a real number between 0 and 1.

25. (Currently Amended) The monitoring system of claim 24, wherein the series function is used to predict the value of $y_{n+1}$ wherein time interval n+1 occurs one time interval after the series of glucose measurement values is obtained.

26. (Currently Amended) One or more microprocessors comprising programming to control

(i) a sensing mechanism to obtain a series of raw signals at selected time intervals, wherein the raw signal is related to an amount or concentration of glucose in a subject, (ii) a first device to obtain ~~either~~ a series of skin conductance readings or a series of temperature readings from the subject, (iii) correlating the raw signals with glucose measurement values indicative of the amount or concentration of glucose present in the subject to obtain a series of glucose measurement values, (iv) predicting a glucose measurement value at a further time interval, which occurs after the series of glucose measurement values is obtained, (v) comparing said predicted glucose measurement value to a predetermined glucose value, wherein a predicted glucose measurement value less than or equal to ~~lower~~ than the

predetermined glucose value is designated to be hypoglycemic, (v) controlling the device for measuring skin conductance readings or temperature readings of the subject, (vi) comparing said skin conductance readings or temperature readings with a threshold skin conductance or temperature ~~parameter~~ value or trend of skin conductance or temperature ~~parameter~~ values to determine whether said skin conductance readings or temperature readings indicate a hypoglycemic event, and (vii) predicting a hypoglycemic event in said subject when both (a) comparing said predicted glucose measurement value to said threshold glucose value indicates a hypoglycemic event at said further time interval, and (b) comparing said skin conductance readings or temperature readings with a threshold skin conductance or temperature ~~parameter~~ value or trend of skin conductance or temperature ~~parameter~~ values indicates a hypoglycemic event.

27. (Original) The one or more microprocessors of claim 26, wherein the sensing mechanism comprises a biosensor having an electrochemical sensing element.

28. (Original) The one or more microprocessors of claim 26, wherein the sensing mechanism comprises a near-IR spectrometer.

36. (Previously Presented) The one or more microprocessors of claim 26, further comprising a second device and wherein said first device comprises a sweat probe to obtain said skin conductance readings and said second device comprises a temperature probe to obtain said temperature readings.

32. (Previously Presented) The one or more microprocessors of claim 36, wherein both skin conductance readings and temperature readings are used to predict the likelihood of a hypoglycemic event at the further time interval.

29. (Original) The one or more microprocessors of claim 26, wherein the selected time intervals are evenly spaced.

31. (Currently Amended) The one or more microprocessors of claim 26, wherein the further time interval occurs one time interval after the series of glucose measurement values.

30. (Currently Amended) The one or more microprocessors of claim 26, wherein the series of glucose measurement values obtained comprises three or more discrete values.

33. (Currently Amended) The one or more microprocessors of claim 30, wherein the predicting a glucose measurement value at a further time interval is carried out using said series of three or more glucose measurement values in a series function represented by:

$$y_{n+1} = y_n + \alpha(y_n - y_{n-1}) + \frac{\alpha^2}{2}(y_n - 2y_{n-1} + y_{n-2}) \qquad (7)$$

wherein $y$ is the measurement value of glucose, $n$ is the time interval between glucose measurement values, and $\alpha$ is a real number between 0 and 1.

34. (Currently Amended) The one or more microprocessors of claim 33, wherein the series function is used to predict the value of $y_{n+1}$ wherein time interval n+1 occurs one time interval after the series of glucose measurement values is obtained.